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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,428	10/15/2001	Peter Unger	B0048-US02	5257
24994	7590	11/14/2003	EXAMINER	
GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,428	Applicant(s) UNGER ET AL.	
	Examiner John Kim	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 6-11 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/7/03 has been entered.

2. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842. WO95/01842 teaches a method of separating cells in a centrifuge comprising providing buffy coat in a processing bag (1) in a centrifuge, separating buffy coat into thrombocyte-rich plasma (i.e. light-weight fraction enriched with platelets), transferring thrombocyte-rich plasma to a storage bag (2) via an outlet tube (3) in a position having a radially inwardly and outwardly directed flow and having an opened clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (3) wherein buffy coat inherently includes platelets and red blood cells whereby the processing bag (1), the storage bag (2), the outlet tube (3) and valve (38) are all disposed in a rotating part of the centrifuge (see figures 5-8; page 8, line 29 - page 10, line 31). Claims 1-3 and 6-8 essentially differ from the method of WO95/01842 in reciting that activation of valve into open position during centrifugation. WO95/01842 teaches that thrombocyte-rich plasma is transferred to a storage bag (2) via an outlet tube (3) having a clamp valve (38) during on-going centrifugation (see page 10, lines 1-31). Furthermore, WO 95/01842 teaches the use of branch conduits placed in clamp valves (38, 39) and that the system with double inner bag chambers i.e. storage bags and branched connector tube between outer and inner bag can be used when a separation into three different fractions

should occur and that two fractions are each led to their respective inner bag and the third remains in the outer bag i.e. processing bag (see page 9, lines 7-34). In order to lead a first fraction into a first inner bag, a clamp valve on a branched connector tube leading to a second inner bag must be closed while a clamp valve on a branched connector tube leading to a first inner bag is in open position. In order to lead a second fraction into a second inner bag, a clamp valve on a branched connector tube leading to a second inner bag must be activated to open position from previously closed position while a clamp valve on a branched connector tube leading to a first inner bag is activated to closed position from previously open position. Activating clamp valve into an open position from a closed position during on-going centrifugation is a necessary step to successfully transfer thrombocyte-rich plasma from a processing bag (1) to a storage bag (2) during centrifugation and this step would have been obvious to a person of ordinary skill in the art.

3. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842 as applied to claim 1 above, and further in view of U.S. Patent No. 5,116,308 (hereinafter referred to as Hagiwara et al). WO95/01842 teaches clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (see page 9, lines 4-11). Hagiwara et al teach the use of manually clamp (41) or electromagnetic valve (41) which is well-known in the art to control the flow of the fluid in an outlet tube from a blood treatment apparatus (see 41 in Figure 2; col. 10, lines 11-25). It would have been obvious to a person of ordinary skill in the art to substitute well-known manually activatable clamp or magnetically activatable valve or

electromagnetically activatable valve for a valve in the outlet tube in the method of WO95/01842 to control the flow of enriched fraction to a storage bag.

4. Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Applicant's arguments filed 7/7/03 have been fully considered but they are not persuasive. Applicants argue that activating a valve to open state is not a necessary step in WO 95/01842. However, WO95/01842 teaches that thrombocyte-rich plasma is transferred to a storage bag (2) via an outlet tube (3) having a clamp valve (38) during on-going centrifugation (see page 10, lines 1-31). Furthermore, WO 95/01842 teaches the use of branch conduits placed in clamp valves (38, 39) and that the system with double inner bag chambers i.e. storage bags and branched connector tube between outer and inner bag can be used when a separation into three different fractions should occur and that two fractions are each led to their respective inner bag and the third remains in the outer bag i.e. processing bag (see page 9, lines 7-34). In order to lead a first fraction into a first inner bag, a clamp valve on a branched connector tube leading to a second inner bag must be closed while a clamp valve on a branched connector tube leading to a first inner bag is in open position. In order to lead a second fraction into a second inner bag, a clamp valve on a branched connector tube leading to a second inner bag must be activated to open position from previously closed position while a clamp valve on a branched connector tube leading to a first inner bag is activated to closed position from previously open position.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
November 10, 2003